ISRCTN64352175 https://doi.org/10.1186/ISRCTN64352175

The impact of indocyanine green (ICG) angiography in multiple diagnostic imaging for the management of exudative age-related macular degeneration (ARMD): a single blind prospective randomised controlled trial of fluorescein angiography vs FA & ICG

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 07/04/2011	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sergio Pagliarini

Contact details
Paybody Eye Unit
Coventry & Warwickshire Hospital
Stoney Stanton Road
Coventry
United Kingdom
CV1 4FH
+44 (0)24 7696 6496
sergio.pagliarini@uhcw.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0295142266

Study information

Scientific Title

Study objectives
Attempt to identify ophthalmic features and positive predictive value for ICG as 'diagnosis and management modifier'. The use of indocyanine gren angiography (ICG) may facilitate the identification of lesions that have been proposed to respond to laser treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised controlled trial and pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Eye Diseases: Age-related macular degeneration (ARMD)

Interventions
Interventions are fluorescein angiography compared with fluorescein angiography and indocyanine green angiography.

Added 05/09/2008: trial was stopped due to new treataments available.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Moderate and severe visual loss defined as loss of three lines or 15 letters (doubling of visual angles) and loss of 6 lines or 30 letters respectively, on a log MAR visual acuity chart, at 4,8 and 12 months.

Secondary outcome measures
1. ICG rates modification of fluorescein based diagnosis and management
2. Specificity and sensitivity of ophthalmic signs predictive of ICG findings

Overall study start date
24/05/2004

Completion date
24/05/2006

Reason abandoned (if study stopped)
New treatments available

Eligibility

Key inclusion criteria
240 patients, of whom 24 are estimated to have retinal angiomatous proliferation (RAP).

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
240

Key exclusion criteria
No specific exclusion criteria

Date of first enrolment
24/05/2004

Date of final enrolment
24/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Paybody Eye Unit
Coventry
United Kingdom
CV1 4FH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospitals Coventry and Warwickshire NHS Trust (UK), NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration